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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,974	07/30/2001	Tanja Ligensa	9515	1210

151 7590 05/19/2003

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/19/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,974

Applicant(s)

LIGENSA ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 24 February 2003 is acknowledged. Claims 1-10 are pending in this application. Claims 1, 2, 8, and 9 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 3-7 under 35 U.S.C., 112, first paragraph, is withdrawn in response to Applicant's amendment. It is newly applied to new claim 10, below.
4. The rejection of claims 3-7 under 35 U.S.C. 112, second paragraph, as being incomplete is withdrawn in response to Applicant's amendment. These claims are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite, below.

Claim Rejections Maintained/New Grounds of Rejection

5. The rejection of claims 3-7 under 35 U.S.C. 112, first paragraph, of record in the office action of paper no. 10, is applied to new claim 10.

Applicant argues that correlation with detecting tumor cell proliferation, escape of apoptosis, and survival is set forth on p. 4. Applicant argues there is sufficient support for the determination of hybridization conditions.

Applicant's arguments with respect to hybridization conditions are found persuasive and this basis of the rejection is withdrawn.

Applicant's arguments with respect to the detection of tumor proliferation, escape of apoptosis, and survival have been fully considered but have not been found to be persuasive.

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The rejection under 35 U.S.C. 112, first paragraph, that was made of record in paper no. 10 with respect to claims 3-7 as they were then written was based on a lack of enablement. While the specification states on p. 4 that activation of the IIP molecules is correlated with tumor proliferation, survival, and apoptosis, the specification does not provide guidance sufficient to allow one of skill in the art to practice the method as it is now claimed in claim 10. As stated in the office action of paper no. 10, all that is provided in the specification are art-standard assays that would allow one of skill to measure IIP levels. There is no guidance to indicate that these levels are correlated with proliferation, with survival, or with the ability to escape apoptosis. There are no working examples or other objective evidence that would allow one of skill to predict that such a correlation would be observed. There is nothing in the specification that indicates that IIP levels are modulated in any way, or that they are correlated with any effects. As stated previously, the prior art fails to provide compensatory teachings. A closely related molecule, GIPC, does not appear to be involved in proliferation, survival, or escape from apoptosis. Thus, based on the instant specification and the teachings of the prior art, one of skill would not predictably be able to use IIP levels as an indicator of these factors. Without further guidance to indicate that the method could be successfully used for this purpose, it would require undue experimentation for one of skill to practice the invention as claimed.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 3-7 are newly rejected under 35 U.S.C. 102(b) as being anticipated by De Vries et al., Proc.Nat. Acad. Sci., 1998, vol. 95, pp. 12340-12345.

As amended, these claims no longer require that the presence of the detected molecule be correlated to proliferative potential. As stated in the office action of paper no. 10, De Vries et al. teaches a polynucleotide 93% identical to instant SEQ ID NO: 1. (It is noted that the journal was incorrectly identified in that action; however, the correct document was supplied to Applicant.) On p. 12341, column 1, and p. 12343, figure 5, De Vries et al. teaches identification of this polynucleotide by Northern blotting. PCR amplification is also taught on p. 12341, column 1. Applicant includes molecules of at least 75% and preferably at least 90% homology to the disclosed sequences as being IIP molecules (p. 9, lines 29-35); thus the sequence taught by De Vries et al. falls within Applicant's definition. De Vries et al. thus teaches detection of an IIP by hybridization with polynucleotides that would hybridize to instant SEQ ID NO: 1, anticipating claims 3 and 4 and further comprise at least a fragment of SEQ ID NO: 1, thus anticipating claim 5, and teaches amplification, anticipating claims 6 and 7.

7. Claims 3-7 and 10 are newly rejected under 35 U.S.C. 112, second paragraph, as indefinite because the claims are now drawn to detection of polynucleotides encoding genes. Polynucleotides encode polypeptides, not genes.

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly


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set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

May 13, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800